REMARKS

Claims 1-29 are pending. Claims 1 and 13 are amended. Claims 6-12 and 14-15 are cancelled. Claims 16-29 are withdrawn. The amendments to the claims find support in the specification and claims as originally filed. No new matter is added.

Sequence Compliance

The Office Action states that the specification does not comply with the sequence requirements of 37 C.F.R. §1.821-1.825 because there are numerous sequences in Figure 8 that do not have sequence identifiers and that are not included in the sequence listing. Applicants are preparing a corrected sequence listing and will file it with the Patent Office under separate cover.

Claim Objections

The Office Action states that claim 7 is objected to for referring to the Fel d I-derived peptides "described in Figure 9." Claim 7 has been cancelled and the objection is, thus, rendered moot. Applicants request that the objection be withdrawn.

The Office Action states that claims 12 and 13 are objected to as being in improper dependent form. Claim 12 has been cancelled and claim 13 has been amended to depend only from claim 1. Accordingly, Applicants request that the objection be reconsidered and withdrawn.

Rejection of Claims 1-7 and 12-13 Under §112, First Paragraph

Enablement

The Office Action states that claims 1-7 and 12-13 are rejected under §112, first paragraph as allegedly failing to comply with the enablement requirement. The Office Action states that the claims are not enabled for a method of desensitizing a patient to a polypeptide allergen by administering to the patient a peptide derived from the allergen wherein the peptide is restricted to a MHC Class II molecule possessed by

the patient, and wherein the peptide induces a late phase response in the individual possessing the MHC Class II molecule. Applicants respectfully disagree and traverse the rejection.

The Office Action states that the specification does not provide support for a method of "desensitization" of a patient to an allergen because the term implies permanent tolerance to the antigen. The Office Action then continues to assert that the claims are not enabled for permanent tolerance. It is well settled law, that an applicant for patent can act as his/her own lexicographer to specifically define terms in a claim. *See, e.g., Hormone Research Foundation Inc. v. Genentech Inc.*, 904 F.2d 1558 (Fed. Cir. 1990). The specification teaches that "desensitizing a patient to a polypeptide allergen" means "inhibition or dampening of allergic tissue reactions induced by allergens in appropriately sensitized individuals" (paragraph 39 of the published application). The definition of "desensitization" does not require that the tolerance must be permanent. Thus, the references cited by the Office Action to suggest that such polypeptide allergen tolerance is not permanent does not corrupt the enablement of the instant claims. In fact, it supports the conclusion that the instant claims are enabled; those of skill in the art have been able to practice the claimed invention as claimed to achieve desensitization as defined in the instant specification.

In addition, the Office Action asserts that the claims are not enabled for administering a peptide derived from the allergen. Applicants respectfully disagree. The Office Action supports its rejection by citing a number of references that allegedly show the unpredictability and adverse reactions that arise from practicing the claimed method. The conclusions drawn by the Office Action from the prior art, however, are not in accordance with the way in which immunotherapy using peptides is considered in the art. Applicants have herewith provided copies of Francis and Larche (2005) Current Opinion in Allergy and Clinical Immunology 5, 537-43, Tarzi et al. (2006) Clinical and Experimental Allergy 36, 465-74, Larche (2005) Pharmacology and Therapeutics 108, 353-61, Ali and Larche (2005) Expert Rev. Vaccines 4, 881-9, Larche (2006) Current Opinion in Immunology 18, 745-50 and Durham et al. (1999) New England Journal of Medicine 341, 468-75 (Exhibits A-F). These articles show that immunotherapy using

peptides is highly effective for treatment of diverse allergic diseases and that long term desensitisation is observed after such immunotherapy. In particular, Francis and Larche, the section at page 537, right hand column, bottom paragraph to page 538, left hand column, second full paragraph which discusses the fact that allergen immunotherapy has been shown to be clinically effective. The other articles support this view, which can be seen by reading the abstracts of the articles.

It is also to be noted that the articles refer at several points to the fact that unpredictable IgE mediated reactions may occur when using whole allergens and that use of peptides avoids such reactions (see for example lines 3 to 9 right hand column page 465 of Tarzi et al. and the abstract of Ali and Larche). Peptides do not cause cross-linking of IgE on mast cells and basophils, and thus adverse reactions are avoided. This is appreciated in the teaching of the present application (see page 27, lines 7 to 9 of the application), and claim 1 is directed to use of peptides, and does not cover use of whole allergens.

The Office Action also cites Francis et al. to argue that desensitising patients using peptides is unpredictable. The full article has been provided with this response. As can be seen from the concluding paragraph of this article, it is acknowledged that short synthetic peptides from allergens have substantially reduced ability to cross-link IgE which means that adverse IgE mediated effects such as anaphylaxis do not occur when using such peptides. Thus, the position taken by the Office Action regarding the unpredictability associated with desensistisation is only applicable to use of whole allergens, and is not relevant to the peptides recited in claim 1.

The Examiner also refers to Kinnunen et al. to again comment on unpredictability. However, this article is written in the context of use of altered peptides, and thus the discussion of unpredictability is centred around whether T cells that recognise the natural sequence are able to cross-react with the altered ligand (see for example the conclusion in the abstract). Further Kinnunen et al. is written in the specific context of use of peptides in autoimmune disease therapy, and therefore is not directly relevant to desensitisation to an allergen.

The standard for determining enablement is whether one of skill in the art could, given the disclosure in the specification and knowledge and skill in the art, make and use the claimed invention without resorting to undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498 (CCPA 1976). Moreover, the fact that experimentation may even be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Wands*.

The Office Action asserts that the claims are not enabled, in part, because one of skill in the art would have to engage in experimentation to practice the full scope of the claimed invention. Applicants disagree. The specification teaches literally hundreds of sequences of allergens that can be used according to the instant claims. The specification further teaches how one of skill in the art can select specific peptides to use in desensitizing a patient (see, e.g., Example 6). Thus, by engaging in the type of routine experimentation, typically performed in the art and described in detail in the specification, one of skill in the art would be able to practice the full scope of the claimed invention.

In view of the foregoing, Applicants note that the art deems immunotherapy using peptides to have a long lived effect and to be predictable. Moreover, the specification and skill in the art would permit the making and using of the claimed invention without undue experimentation. Accordingly, Applicants request that the rejection be reconsidered and withdrawn.

Written Description

The Office Action states that claims 1-7 and 12-13 are rejected as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors were in possession of the claimed invention. As noted in the Office Action, adequate written description for a claimed genus may be satisfied through sufficient description of a representative number of species. As noted above, the specification teaches hundreds of species of

polypeptide allergens and peptides thereof that can be used in according to the instant claims. Thus, the specification discloses a representative number of species of the claimed genus. Furthermore, appropriate peptides for desensitising an individual to an allergen could be obtained by routine means. As can be seen from claim 1 the peptides are required to have restriction to a MHC Class II molecule, i.e. they comprise sequence which binds to a MHC class II molecule. In order deduce the presence of such sequence within the allergen, fragments of the allergen may be tested for binding to a MHC Class II molecule, for example using the techniques described in Example 5 and 6 of the application.

The invention relies on generation of a late phase response using the peptides defined in claim 1. This response is stimulated by T cells recognising peptide sequence after it has become bound to the appropriate MHC class II molecules on the surface of cells of the individual. Thus the invention is applicable to an allergen that comprises a sequence that demonstrates restriction to a MHC class II molecule. Given that a common desensitisation mechanism exists which can be used to tolerise against an allergen that contains sequence which demonstrates restriction to a MHC class II molecule, then no further description is needed of the peptide sequences for the skilled person to carry out the invention, and there is adequate written description in the application as filed. Accordingly, Applicants request that the rejection be reconsidered and withdrawn.

Rejection of Claims 1-7 and 12-13 Under 35 U.S.C. §102(b)

The Office Action states that claims 1-7 and 12-13 are rejected under §102(b) as anticipated, separately, by WO97/35193, WO91/06571, WO93/08280, and Norman et al. Applicants traverse the rejection in view of the claims as herein amended.

Each of the cited references allegedly discloses the use of Fel d I peptides. Claim 1, however, has been amended to exclude use of Fel d I derived peptides. Thus the claims are novel over the documents cited by the Office Action which all discloses use of Fel d I peptides. In addition given that none of the documents cited by the Office Action refer to desensitising a patient using a peptide that shows restriction to a Class II

molecule and is able to induce a late phase response then the present claims are also not obvious from the cited documents. Accordingly, Applicants request that the rejections under §102(b) be reconsidered and withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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